

PATENT COOPERATION TREATY


PCT

REC'D 07 JUL 2005

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

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|---|--|---|--|--|
| Applicant's or agent's file reference P35509WO/NCB | | FOR FURTHER ACTION | | See Form PCT/IPEA416 |
| International application No. PCT/IB2004/001702 | | International filing date (day/month/year) 23.04.2004 | | Priority date (day/month/year) 23.04.2003 |
| International Patent Classification (IPC) or national classification and IPC A61K9/28, A61K9/20 | | | | |
| Applicant JAGOTEC AG | | | | |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau) a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> | | | | |
| <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the International application</p> | | | | |
| Date of submission of the demand 22.11.2004 | | Date of completion of this report 08.07.2005 | | |
| Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016 | | Authorized Officer Boulois, D Telephone No. +31 70 340-3878 | | |



**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/IB2004/001702

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-18 as originally filed

Claims, Numbers

1-10 as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|----------|
| Novelty (N) | Yes: Claims | 2-4, 6-8 |
| | No: Claims | 1,5,9,10 |
| Inventive step (IS) | Yes: Claims | 2-4, 6-8 |
| | No: Claims | 1,5,9,10 |
| Industrial applicability (IA) | Yes: Claims | 1-10 |
| | No: Claims | |

2. Citations and explanations (Rule 70.7):

see separate sheet

**INTERNATIONAL PRELIMINARY
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(SEPARATE SHEET)**

International application No.

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Re Item V.

1. The following documents are referred to in this communication:

D1 : US 3 125 491 A (ELOWE L. N ET AL) 17 March 1964 (1964-03-17)

D2 : US 3 048 526 A (BOSWELL CHARLES L) 7 August 1962 (1962-08-07)

D3 : EP 0 519 099 A (SQUIBB BRISTOL MYERS CO) 23 December 1992 (1992-12-23)

2. The present application does not satisfy the criterion set forth in Article 33(2) PCT because the subject-matter of claims 1,5,9,10 is not new in respect of prior art as defined in the regulations (Rule 64(1)-(3) PCT).

Document D1 discloses a compressed coated tablet with a colorant in the core (see example 1). The composition disclosed in D1 is granulated with a solution comprising a red dye F.D. and C (see col. 3, l. 23-30) which is therefore comprised within the core composition and not coated around the core. It is considered that any dye will contrast the core from the coating, since it provides a different colour to the core. In addition red dye F.D. and C is cited in the present application as a suitable dye (see the description of the present application, page 4, l. 25-31).

This core composition is further coated by a sugar coating.

Consequently, the subject-matter of claims 1,5,9,10 is not new over D1 (Article 33(2) PCT).

Document D2 discloses a compressed coated tablet with a different colour in the core than in the mantle (see col. 5, l. 35-41). This is used to control the final tablet. The mantle coating does however not surround completely the core composition.

D3 relates to compression coated formulations with a colorant in the external part of the tablet (see example 1).

3. The document D2 appears to be of particular relevance as far as inventive step is concerned (Article 33(3) PCT). This document addresses a slightly different problem than the present application, namely making a tablet with colour as direct mean of visual control. The problem of control of the displacement of the core is therefore not related in this document, which does not disclose a complete surrounding coating.

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The skilled person would not try to change the characteristics of document D2 to solve the problem of the present application as far as novel.

Consequently, the subject-matter of claims 2-4, 6-8 is inventive over D2 (Article 33(3) PCT).